A Study of Efficiency of Autologous Platelet Rich Plasma in Myringoplasty

Dr. Ramya Rajalakshmi. K*

3rd Year Postgraduate, Department of ENT, Sri Manakula Vinayagar Medical College Hospital and Research Centre, Puducherry, India

***Abstract*:**

Background: Chronic suppurative otitis media is defined as chronic inflammation of the mucoperiosteal lining of the middle ear cleft. It is associated with a persistent or intermittent infected discharge through a non-intact tympanic membrane. PRP is proven to be effective in aiding the graft uptake in myringoplasty in various studies. Platelet rich plasma is also effective in preventing the recurrence of perforation, thus avoiding repeated surgeries. It can also aid in hearing improvement. Hence the patients show greater degree of satisfaction with the surgery.

Methodology: Hospital based Cross sectional study was conducted on the patients attending the out-patient department of ENT department at SMVMCH, who have undergone Myringoplasty within the duration of 18 months. The data collection was done for a period of 18 months after obtaining approval from the Institutional Ethics Committee. For all the selected patients, a thorough history and examination was conducted. The patients with PRP application were grouped under study group and those with conventional surgery were grouped under control group until the required sample size is attained. Both the groups had undergone PTA and otoendoscopy preoperatively. And 8 weeks post-operatively patient was subjected to PTA and otoendoscopy. results were collected and analysed.

Results: The average PTA value was 24 in control group and 30 in control group. And the hearing improvement is better in the group with PRP application which was statistically significant. It was found in PRP group 96.9% of patients had healthy graft and 3.1% had recurrent perforation whereas in control group 78.1% had healthy graft and 21.9% had recurrent perforation**.**

Conclusions: The platelet rich plasma in Myringoplasty was found to be highly efficient. It was found to improve graft uptake and PTA value. It was also found to improve the hearing in patients when compared to patients who had not undergone PRP application. Platelet Rich Plasma, being safe, autologous and easily prepared can be applied over graft in "Myringoplasty for better outcomes and reduced failure rates.

Keywords: Myringoplasty, platelet rich plasma, hearing improvement in Myringoplasty, temporalis fascia graft, chronic otitis medi

Introduction:

Chronic otitis media is one of the challenges faced by Otorhinolaryngologists which is clinically marked by recurrent disease exacerbations. To make ear dry and restore hearing loss, the surgical technique adapted commonly is Myringoplasty. However, the success of the surgery is evaluated by measuring the improvement in hearing and perforation healing. Various studies have been conducted and it is found that the failure rate for temporalis fascia graft ranges from 26 to 44% in adults and may go up to 65%in children. [1] Platelet Rich Plasma is proven to be effective in aiding the graftuptake in myringoplasty in various studies. [2,3] Procuring platelet rich plasma is a minimally invasive, easy and safe technique. Numerous studies have been conducted to show high success rates of perforation healing and hearing improvement with use of platelet rich plasma in myringoplasty in various population all over the world. [4] Following this background literature, this study is conducted to evaluate the efficacy of platelet rich plasma in Myringoplasty among patients with chronic otitis media attending Sri Manakula Vinayagar Medical College. All the factors that influence perforation healing like immunocompromised state, chronic medical illness, debilitating illness, substance abuse etc. have been excluded from the study to accentuate the authenticity of the study. Platelet rich plasma is also effective in preventing the recurrence of perforation, thus avoiding repeated surgeries and aids in hearing improvement. Hence the patients show greater degree of satisfaction with the surgery.

Objective:

To study the efficiency of use of platelet rich plasma in closure of tympanic membrane during Myringoplasty.

To evaluate the hearing improvement after myringoplasty with Platelet rich plasma.

Materials And Methods:

Study Setting:

Hospital based study was conducted in the DEPARTMENT OF OTORHINOLARYNGOLOGY in Sri Manakula Vinayagar Medical College and Hospital (SMVMCH), Puducherry. SMVMCH is an ultramodern tertiary hospital maimed by skilled medical service providers. The beneficiaries of the hospital expand across 40 nearby villages of both Puducherry and Tamil Nadu. This hospital is equipped with 1180 beds and 250 ICU beds. All patients receive comprehensive medical care with multidisciplinary approach and high quality of care across all platforms from primary care to complex surgical intervention. The department of Otorhinolaryngologycaters to about 100 outpatients and an average of 4 surgeries on day-to-day basis.

Study Design:

Hospital based Cross sectional study.

Study Participants:

The study was conducted on all patients attending the out-patient department of ENT department at SMVMCH, who meet the eligibility criteria and have undergone Myringoplasty within the duration of 18 months.

Sample Size:

Based on the sample study conducted by Anwar et al, the hypothesized frequency of outcome factor is 88.57% with the confidence level 95% and absolute precession 7.9%the sample size was calculated as 63 for the study. It was decided to include all the consenting patients who have undergone myringoplasty in our hospital during the studyperiod. [5]

Sampling Method:

The inclusion criteria include the Patients with Chronic otitis media, inactive mucosal disease without discharge, for a minimum of 6 to 8 weeks (central perforation with dry ear), who underwent myringoplasty during the study period. The exclusion criteria include Children below 12 years of age, active ear disease, atopy and allergic rhinitis, Chronic medical illnesses like diabetes mellitus, other debilitating systemic illness like autoimmune disease, active neoplastic disease, substance use disorders, and patients on immunosuppressant drugs.

The study participants were divided into study group and control group. A total of 33 patients who underwent myringoplasty with application of platelet rich plasma during the same study period were taken as the study group. A total of 32 patients who underwent myringoplasty without the use of platelet rich plasma during the same study period were taken as control group.

Study Duration:

The data collection was done for a period of 18 months (November 2022 to December 2023) after obtaining approval from the Institutional Ethics Committee

Data Collection Procedure:

For all the selected patients, a thorough history and examination was conducted. The patients with PRP application were grouped under study group and those with conventional surgery were grouped under control group until the required sample size is attained. Both the groups had undergone PTA and otoendoscopy preoperatively. The results were collected and analyzed. For the patients under study group, 10 ml of blood sample was collected in a container with 1 ml of anticoagulant. The blood collected is centrifuged with an automatic centrifugation machine at 3200rpm for 12mins which produced three layers in the container. Top layer contains supernatant platelet poor plasma, middle layer contains about 1.5ml of PRP and RBCs are present in the bottomlayer. The layer of PRP was extracted using pipette and used during the surgery.[5] For the patients who underwent conventional surgery, plain gel form was applied during myringoplasty. All the patients who came for follow up at 8 weeks postoperatively were subjected for investigations which included otoendoscopy and PTA. The data was compared between the study group and control group.

Data Analysis:

Data will be entered in the Epi Info program and then analyzed. Percentage was used fro categorical variables. Mean and standard deviations was used

for continuous variables. Chi square test was used for categorical variable comparison. T test was used for continuous variable comparison. Pearson correlation was used for more than 2 continuous variable correlation.

Ethical Consideration:

This study was carried out after obtaining approval from the ethical committee of the Institute Ethics committee. (EC/96/2022).

Reporting Of The Study:

The study was reported following STROBE guidelines

Results:

Descriptive Data:

Table 1: descriptive data compared between both groups

Variable	Study group	Control group
Age of patient	32.39	27.63
Sex of patient	Equal	Equal
Side of the ear	UL>BL	UL>BL
Duration of illness	10-15 years	10-15 years
Pre-operative PTA	35.58	32.81
Type of hearing loss	Conductive Hearing Loss	Conductive Hearing Loss
Pre-operative otoendoscopy	Moderate Central Perforation	Moderate Central Perforation
Post-operative PTA	24.70	30.41
Post-operative difference in PTA	10.64	2.41
Post-operativ eotoendoscopy	Healthy graft (96.9%)	Healthy graft (78.1%)

The above table shows that the data compared between the groups are identical

Table 2: Pre-operative Hearing Loss Vs post-operative Hearing Loss

	NORMAL	CHL	SNHL	MIXED HL	P Value
STUDY GROUP					
CHL	16	6	0	0	0.000
Mixed HL	0	9	2	0	
CONTROL GROUP					
CHL	1	23	1	0	0.000
Mixed HL	0	0	5	2	

In the PRP group, about 100% of the post-operative normal hearing was observed in the preoperative conductive hearing loss group. Also 6 participants out of 22 participants of the pre-operative conductive hearing loss had residual conductive hearing loss.

Whereas, In the control group, there was only one participant with post-operative normal hearing which was observed in the preoperative conductive hearing loss group. Also all post-operative mixed hearing loss was reported in the pre-operative mixed hearingloss.

These observations in both the groups were statistically significant. (p=0.000**)

Table 3: Significance of post-operative otoendoscopy in both the groups

Post-operative Otoendoscopy	PRP group		Control group		Pearson's chi Square
	Frequency	Percentage	Frequency	Percentage	Value
Healthy graft	32	96.9	25	78.1	5.346
Recurrent perforation	1	3.1	7	21.9	P
Total	33	100	32	100	0.021*

Above table shows that 32 out of 33 accounting 96% had healthy graft on 8 weeks follow-up otoendoscopy. However, control group had only 78% healthy graft.

The difference in post-operative otoendoscopy findings among both the groups were statistically significant. (p= 0.021*).

Table 4: Significance of association between pre-

	MEAN	Correlation	P	95% CI
			Lower	Upper
Pre-operative PTA vs Post-operative PTA				
Study group	**10.87 (5.08)**		**0.807**	**0.000**
9.076	**12.682**			
Control group	**2.406(4.08)**		**0.850**	**0.002**
0.933	**3.880**			
Age of the patient vs Post-operative hearing Improvement				
Study group	**21.75**	**-0.130**	**0.000**	**17.77**
25.73				
Control group	**25.21(11.42)**		**-0.049**	**0.000**
21.10	**29.33**			

operative type of hearing loss andpost-operative type of hearing loss in PRP group

Pre-operative hearing loss	Hearing loss at 8 weeks post-operative follow-up				Pearson's chi square
	Normal	Conductive hearing loss	Sensorineural hearing loss	Mixed hearing loss	Value
Conductive hearing loss	16	6	0	0	16.800
Mixed hearing loss	0	9	2	0	p
Total	16	15	2	0	0.000*

In the PRP group, about 100% of the post-operative normal hearing was observed in the preoperative conductive hearing loss group. Also 6 participants out of 22 participants of the pre-operative conductive hearing loss had residual conductive hearing loss.

The mean of variables had a positive linear correlation which was strongly significant with (p=0.000**) in study group and (p=0.002*) in control group.The age of the patient and post-operativehearing improvement had linear negative correlation which was statistically significant (p=0.000**) in both the groups.

Discussion:

This study was conducted to assess the efficiency of platelet rich plasma in myringoplasty in terms of graft uptake and hearing improvement. A total of 65 patients were selected randomly and studied retrospectively. On comparing the dempographic profile of both the groups, they was identical and homogenous. The hearing improvement was significant in both the groups. However the hearing improvement was more among the PRP group. The post-operative otoendoscopy in both groups showed better graft uptake among the PRP group. The study also showed that the hearing improvement was better in younger patients.

The study that was conducted by M.K.Taneja et al, among 82 samples showed the hearing improvement in control group was 46.3% whereas in PRP group it was 78.0% which was statistically significant.[4] A study conducted by S Gokce Kutuk et al showed that the temporalis fascia graft with platelet rich plasma showed better survival rate which was 100% in one month.[7] however, According to the randomised control trial conducted by Prity Sharma et al the graft uptake was 94.1% in PRP group and it was 92.1% in control group with p=0.358 which was statistically insignificant.[8] The prospective study conducted by Mohammad Waheed El-Anwar et al showed that 21 out of 25 patients had successful perforation repair.[5] S P S Yadav et al showed that among 40 patients who were divided into 2 groups with 20 each, the graft uptake was 95% in PRP group and 85% in controlgroup with p<0.03 which was statistically significant.[9] The study conducted by Juntao Huang et al among 455 participants showed that the OR of perforation closure was 3.69 which was statistically significant.[10]

Strengths Of The Study:

1. PRP, being a novel technique for reconstruction procedures, has been used in various disciplines. But its use in otorhinolaryngology is limited. However, the use of PRP in Myringoplasty to improve the

graft uptake has been a field of interest in the recent days. A very few studies have been conducted on the use of PRP in Myringoplasty to improve graft closure and hearing improvement.

2. Temporalis fascia graft which is better graft material for myringoplasty was used so that the efficiency of PRP on hearing improvement can be concenterated.
3. Since autologous PRP was used, it is easy to procure and safe to use.
4. The demographic profile that was selected was a representative of the population, as supported by the previous studies
5. In this study both the graft uptake and hearing improvement have been evaluated in this study among the same population evaluating the effect of PRP in perforation closure following Myringoplasty.
6. The graft uptake and hearing improvement have been evaluated by otoendoscopy and standard PTA tests both preoperatively and postoperatively at 8 weeks. Hence, the results are reliable.
7. Other factors like age that affect the hearing improvement and graft uptake was also identified.
8. The study also shows the Myringoplasty improves hearing with or without PRP.
9. The study also compares various other factors like duration of illness, type of hearing loss, pre-operative otoendoscopy with the hearing improvement and post-operative otoendoscopy.
10. Patients who underwent Myringoplasty with PRP benefited better chances of hearing improvement and graft uptake.

Limitations:

1. The study included only the data at time of postoperative visit and the history of the patient retrospectively. Adequate and frequent follow up could show detailed healing process and evaluation of the graft status frequently which can be done by other study designs
2. The study did not include the educational status, occupation, economic status which might influence the graft care that would be given by the patients at home after discharge.
3. The patients with comorbid illness were excluded from the study. The healing process and graft uptake could also be assessed after application of PRP in these patients.
4. The duration of surgery and the intraop complications were unknown as it was cross sectional study
5. Various factors like ossicular status that influence the post-operative hearing were not known.
6. The study was not blinded so bias could be present.

Conclusion:

The platelet rich plasma in Myringoplasty was found to be highly efficient. It was foundto improve graft uptake and PTA value. It was also found to improve the hearing in patients when compared to patients who had not undergone PRP application. Platelet Rich Plasma, being safe, autologous and easily prepared can be applied over graft in Myringoplasty for better outcomes and reduced failure rates.

Reference:

1. Watkinson, J., & Clarke, R. (Eds.). (2018). Scott-Brown's Otorhinolaryngology and Head and Neck Surgery: Volume 2: Paediatrics, TheEar, and Skull Base Surgery (8th ed.). CRC Press. https://doi.org/10.1201/9780203731017
2. Stavrakas M, Karkos PD, Markou K, Grigoriadis N. Platelet-rich plasma in otolaryngology. J Laryngol Otol. 2016 Dec;130(12):1098-1102. doi: 10.1017/S0022215116009403. PMID: 27938467.
3. Akash, Datta R, Suri GS, Mucha S, Sheikh MA, Taneja NS. A Randomised Controlled Trial on the Efficacy of Topical Application of Autologous PlateletRich Plasma (PRP) on Graft Uptake Rate in Adults Undergoing Type 1 Tympanoplasty for Inactive COM Mucosal Disease. Indian J Otolaryngol Head Neck Surg. 2023 Apr;75(Suppl 1):605-613. doi: 10.1007/s12070-023- 03681-w. Epub 2023 Mar 16. PMID: 37206740; PMCID: PMC10188864.

4. Taneja MK. Role of Platelet Rich Plasma in Tympanoplasty. Indian J Otolaryngol Head Neck Surg. 2020 Jun;72(2):247-250. doi: 10.1007/s12070- 020-01815-y. Epub 2020 Feb 13. PMID: 32551285; PMCID: PMC7276456.

5. El-Anwar MW, El-Ahl MA, Zidan AA, Yacoup MA. Topical use of autologous platelet rich plasma in myringoplasty. Auris Nasus Larynx. 2015 Oct;42(5):365-8. doi: 10.1016/j.anl.2015.02.016. Epub 2015 Mar 17. PMID:25794691.

6. Kumar RD. Application of Platelet Rich Fibrin Matrix to Repair Traumatic Tympanic Membrane Perforations: A Pilot Study. Indian J Otolaryngol Head Neck Surg. 2019 Nov;71(Suppl 2):1126-1134. doi: 10.1007/s12070-017-1239- 6. Epub 2017 Dec 2. PMID: 31750137; PMCID: PMC6841996.

7. Gökçe Kütük S, Özdaş T. Impact of platelet-rich fibrin therapy in tympanoplasty type 1 surgery on graft survival and frequency-specific hearing outcomes: a retrospective analysis in patients with tympanic membrane perforation due to chronic otitis media. J Laryngol Otol. 2019 Dec;133(12):1068-1073. doi: 10.1017/S0022215119002391. Epub 2019 Nov 18. PMID: 31735178.

8. Sharma P, Parida PK, Preetam C, Mukherjee S, Nayak A, Pradhan P. Outcome of Temporalis Fascia Myringoplasty With and Without use of Platelet Rich Plasma: A Randomized Control Trial. Indian J Otolaryngol Head Neck Surg. 2022 Dec;74(Suppl 3):3832-3840. doi: 10.1007/s12070-021-02615-8. Epub 2021 May 28. PMID: 36742679; PMCID: PMC9895725.

9. Yadav SPS, Malik JS, Malik P, Sehgal PK, Gulia JS, Ranga RK. Studying theresult of underlay myringoplasty using platelet-rich plasma. J Laryngol Otol. 2018 Nov;132(11):990-994. doi: 10.1017/S0022215118001846. Epub 2018 Oct 29. PMID: 30370872.

10. Huang J, Teh BM, Zhou C, Shi Y, Shen Y. Tympanic membrane regeneration using platelet-rich fibrin: a systematic review and meta-analysis. Eur Arch Otorhinolaryngol. 2022 Feb;279(2):557-565. doi: 10.1007/s00405-021-06915- 1. Epub 2021 Jun 4. PMID: 3408608